TMJ IMPLANTS
INCORPORATED

TMJ Metal-on-Metal Total Joint Replacement Prostheses System

comprised of the

TMJ Fossa Eminence and Condylar Prostheses

Instructions for Use

Products distributed in the United States

TMJ Fossa Eminence Prostheses

Right Side Kit
(Models FER-01 through FER-33)

Left Side Kit
(Models FEL-01 through FEL-33)

Supplemental Kit – Right/Left
(Models FER-34 through FER-44, FEL-34 through FEL-44)

TMJ Patient-Specific™ Fossa-Eminence Prosthesis
(Models CFER and CFEL)

TMJ Condylar Prostheses

TMJ Universal Arthro-Chrome™ Condylar Prosthesis System
(Models R/LMCP-45, R/LMCP-50, R/LMCP-55)

TMJ Patient-Specific™ Condylar Prosthesis
(Models CRMCP and CLMCP)

TMJ Christensen/Chase Arthro-Chrome™ Condylar Prosthesis System
(Models C/C-RMCP-45, C/C-RMCP-50, C/C-RMCP-55, C/C-LMCP-45, C/C-LMCP-50, C/C-LMCP-55)

CE 0344 STERILE R

Store between 10° and 32°C (50° - 90°F) and 20% to 80% relative humidity.

Manufactured by

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5 New Quebec Street
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44-20-77247-008

Caution: United States Federal Law restricts this device to sale by or on the order of a physician.

1. DEVICE DESCRIPTION

The TMJ Metal-on-Metal Total Joint Replacement System is comprised of the TMJ Fossa Eminence and Condylar Prostheses, respectively.

The TMJ Fossa-Eminence Prosthesis

The TMJ Fossa-Eminence Prosthesis is designed to provide a thin, rigid, well-fitting prosthetic covering for the articulating surface of the temporomandibular joint comprised of the glenoid fossa and articular eminence of the temporal bone. The articular surface of the prosthetic glenoid fossa and articular eminence is highly polished to minimize friction in joint movement.

The prosthesis, and the screws with which it is to be secured to the skull, are manufactured from surgical Co-Cr-Mo alloy (ASTM F75/ASTM F799). These devices are intended for permanent implant and are for single use only.

All components in this Fossa kit, including individual prosthesis, drills and screws are sterilized by gamma-irradiation or e-beam radiation (2.5 Mrads), and are packaged in individual double-peel PETG and Tyvek containers.

Two additional NON-STERILE Fossa kits accompany this TMJ Fossa-Eminence Prosthesis System and are essential for its use. The Fossa-Eminence Trial Sizing System contains trial sizer components for each size of implant. The Instrument Kit contains screwdrivers and Fossa-Eminence holders.

These two accompanying kits must be steam sterilized prior to use in accordance with procedures outlined in Sections 8 and 9.

The TMJ Condylar Prosthesis

The TMJ Condylar Prosthesis, which is intended to be used with the Fossa Eminence for total joint replacement, is designed to replace the articular surface of the mandibular condyle.

The TMJ Condylar Prostheses systems are designed to seat against the TMJ Fossa-Eminence Prosthesis and to be secured to the ramus of the mandible with cobalt chrome alloy screws. The Universal prosthesis is manufactured in three lengths, and is designed to be used on either the right or left side. The Christensen/Chase Condylar Prosthesis is also available in three lengths and is manufactured specifically for either the right or left side.

The entire Arthro-Chrome™ prosthesis and the screws with which they are to be secured to the mandible, are manufactured from surgical Co-Cr-Mo alloy (ASTM F75/ASTM F799). These devices are intended for permanent implant and are for single use only.

All components in the Condyle Prosthesis kit, including individual prosthesis, drills and screws are sterilized by gamma-irradiation or e-beam radiation(2.5 Mrads), and are packaged in individual double-peel PETG and Tyvek containers.

Two additional Condyle kits accompany this TMJ Condylar Prosthesis System and are essential for its use. The Condylar Trial Sizing System contains sterile disposable trial

sizer components for each size of implant, as well as a sizing template. The NON-STERILE Instrument Kit contains screwdrivers and holders.

The accompanying instrument kit must be steam sterilized prior to use in accordance with procedures outlined in Sections 8 and 9.

2. INTENDED USE/INDICATIONS

The TMJ Metal-on-Metal Total Joint Replacement System is intended for use in treatment of severe temporomandibular joint disease. The TMJ Condylar Prosthesis is intended for use in conjunction with the TMJ Fossa-Eminence Prosthesis whenever total joint reconstruction is necessary due to:

- Inflammatory arthritis involving the temporomandibular joint not responsive to other modalities of treatment
- Recurrent fibrous and or bony ankylosis not responsive to other modalities of treatment
- Failed tissue graft
- Failed alloplastic joint reconstruction
- Loss of vertical mandibular height and/or occlusal relationship due to bone resorption, trauma, developmental abnormality or pathologic lesion.

3. CONTRAINDICATIONS

The TMJ Metal-on-Metal Total Joint Replacement System should not be used for patients with one or more of the following conditions:

- Infection or malignancy in the head or neck region
- Known allergy to any of the components of the system
- Ability to exert significant post-operative masticatory muscle hyperfunction (clenching or grinding) which may lead to overload and fracture of the device or loosening of the screws

4. WARNINGS

Dynamic fatigue tests were conducted on the TMJ Implants Metal-on-Metal Total Joint Replacement System with a force applied vertically to the device. No failures occurred at 130 lbs. Physicians should carefully consider the results of these fatigue tests when patients present with particular anatomical considerations or unusual masticatory forces.

- TEST FOR ANY SUSPECTED SENSITIVITY TO MATERIALS.

Patients with suspected sensitivity to metals, such as Nickel, should undergo appropriate testing for sensitivity to Co-Cr-Mo alloy. Upon request, TMJ Implants, Inc. will supply a sample of this alloy and/or the chemical composition for pre-operative allergy testing. The device should not be used in patients who test positive for Co-Cr-Mo alloy sensitivity.

- IF LONGER SCREWS ARE NECESSARY:

Occasionally, longer screws will be necessary to engage bone. It is important that the surgeon exercise great care to prevent injury to deeper vital structures. Care must be exercised not to penetrate or impinge any auditory structure, middle cranial fossa, or any neuro/vascular structures.

- IF EXCISING BONE:

When performing an excision of bone in the area of the normal glenoid fossa and condyle, especially in cases of bony ankylosis, the surgeon must exercise great care to avoid penetration into the middle cranial fossa, the auditory canal, or other vital structures.

5. PRECAUTIONS

Prior to Surgery

- Special attention should be paid to patient selection. Careful evaluation should be made of patients with disorders that might interfere with their ability to comply with the limitations and precautions necessary to achieve beneficial outcome from this implant.
- All TMJ Metal-on-Metal Total Joint Replacement Prostheses, screws, drills, and the Condyle sizers are provided sterile. Inspect sealed sterile package before opening. If seal is broken, do not use. Do not resterilize.
- Prior to use, the Instrument Kit containing screwdrivers and Fossa-Eminence holders must be sterilized as outlined in Sections 8 and 9.
- The surface of the device must remain clean and free of debris prior to implantation.
- The implant must be handled only with talc-free gloves to avoid introduction of talc into the implantation site.
- The prostheses must be protected from scratching or bending prior to and during surgical implantation, as such damage may cause weakening or fatigue of the metal or fracture of the part.

During Surgery

- The TMJ Prosthesis System must be secured only through the use of the drills and screws supplied by TMJ Implants, Inc. The screws and drills used with the TMJ Prosthesis System have been specifically selected by size to ensure correct fixation of each prosthesis when used as directed. Any use of substitute drill bits or screws not supplied by TMJ Implants, Inc. in the TMJ Prosthesis System may result in less than optimal long-term results and may adversely affect the performance of the prosthetic device.
- It is strongly recommended that at least four (4) Fossa-Eminence screws be used where practical to achieve firm fixation of the TMJ Fossa-Eminence Prosthesis.

- It is strongly recommended that at least six (6) condylar screws for the Universal Condylar Prosthesis and nine (9) condylar screws with the Christensen-Chase Condylar Prosthesis be used, where practical, to achieve firm fixation of the TMJ Condylar Prosthesis. Care must be taken to secure at least 3 screws in the topmost holes, where practical.
- It is recommended that the head of the TMJ Condylar Prosthesis be placed into the prosthetic glenoid fossa portion of the TMJ Fossa-Eminence Prosthesis with all interposing soft tissue removed. The Condylar Prosthesis articulating surface should preferably be centered in the Fossa and should not contact the screws of the Fossa-Eminence Prosthesis.

6. ADVERSE EVENTS

Adverse events observed in the clinical use of the TMJ Implants, Inc. Metal-on-Metal Total Joint Replacement System are listed below (in descending order of frequency of occurrence.)

- Postoperative pain, swelling, jaw muscle spasm (10 subjects)
- Facial nerve and muscle weakness or paralysis (9 subjects)
- Dislocation of the joint (2 subjects)
- Infection (2 subjects)
- Degenerative joint changes and development of adhesions (2 subjects)
- Nausea and vomiting (2 subjects)
- Perioperative bleeding (1 subject)
- Seizures (1 subject)
- Malocclusion (1 subject)

In addition to the adverse events identified above, potential adverse events and complications associated with temporomandibular joint surgery and reconstruction may require further treatment and include but are not limited to:

- Hematoma formation
- Hemorrhage
- Dental malocculsion, jaw dysfunction, limited range of motion
- Foreign body or allergic reactions to the device materials
- Rejection of the device
- Wear, displacement of the device or implant loosening
- Fracture of the device
- Hearing problems
- Surgical damage to anatomical structures adjacent to the TMJ
- Patient discomfort
- Speech problems
- Facial deformity

7. CLINICAL DATA

Two studies were conducted that support the safety and effectiveness the TMJ Implants, Inc. Metal-on-Metal Total Joint Replacement System. The first is the TMJ Implants, Inc. Registry; the second a prospective clinical study.

The objectives of these studies were to demonstrate that the TMJ Implants, Inc. Metal-on-Metal Total Joint Replacement System [TMJ ArthroChrome condylar prosthesis used in conjunction with a TMJ Fossa-Eminence Prosthesis (total joint replacement)] significantly reduces TMJ pain and improves interincisal opening.

An additional objective of the Prospective Study included a review of the incidence of device related adverse events occurring during the study.

For each study, pain measurements were recorded using a 10cm Visual Analog Scale (VAS). The left side of the scale represented no pain while the right side represented the most severe pain imaginable. The patients' were instructed to mark a vertical line on the scale to indicate their perceived level of pain. Interincisal opening was measured in millimeters using a Therabite Scale. The interincisal opening was measured at the point at which the patient cannot open his/her mouth any wider.

Target Population

The target population for a TMJ metal-on-metal total joint replacement utilizing the TMJ Condylar prosthesis in conjunction with the TMJ Fossa-Eminence prosthesis are those patients suffering from deficiencies of the natural condyle in cases of serious adhesion, condylar destruction, ankylosis, avascular necrosis, intrinsic bone disease (neoplasia), congenital disease involving the TMJ, rheumatoid arthritis, osteoarthritis, foreign body giant cell reaction, previous failed implant surgery, or other pathology with resultant occlusal or functional deficiency.

TMJ Implants, Inc. Registry

Demographics

There were 425 total joint recipients representing 1309 devices included in the cross-section data set and 63 patients representing 204 devices in the cohort data set. The majority of the patients in each group received "stock" devices. There were 267 patients (63%) with stock devices in the cross-section group, of which 25 (6%) were of the Christensen/Chase model. There were 36 patients (57%) in the cohort group with stock devices of which 10 (16%) were of the Christensen/Chase model. The mean age of the cross-section group of patients was 42±12 years and 41±12 years for the cohort. There were 89% female in the cross-section and 91% female in the cohort. No difference between age and gender among the cross-section group and cohort was demonstrated, $p>0.05$.

Reduction in Pain and Diet Restriction: Total Joint Reconstruction

From the Cross-section data set, there is a marked reduction in pain and diet restriction within the first month after surgery, as demonstrated by Figure 1. Patients appear to reach their greatest relief within 6 months of surgery and maintain that level of

improvement or slightly above through 4 years implant duration. A similar trend of pain reduction is demonstrated with a cohort of 63 patients with complete data through 2 years implant duration, Table 2. Approximately one-third of the cohort has complete data at 3 years. These data are not included in the analysis. By applying a test of contrasts to the 2-year cohort, a significant reduction in pain at every time period is demonstrated when compared to the pre-op value, $p<0.0001$. Additionally, an ANOVA F-Test was applied to the cohort. The overall test is significant at $p<0.0001$.

Figure 1: Total Joint, Reduction in Pain and Diet Restriction

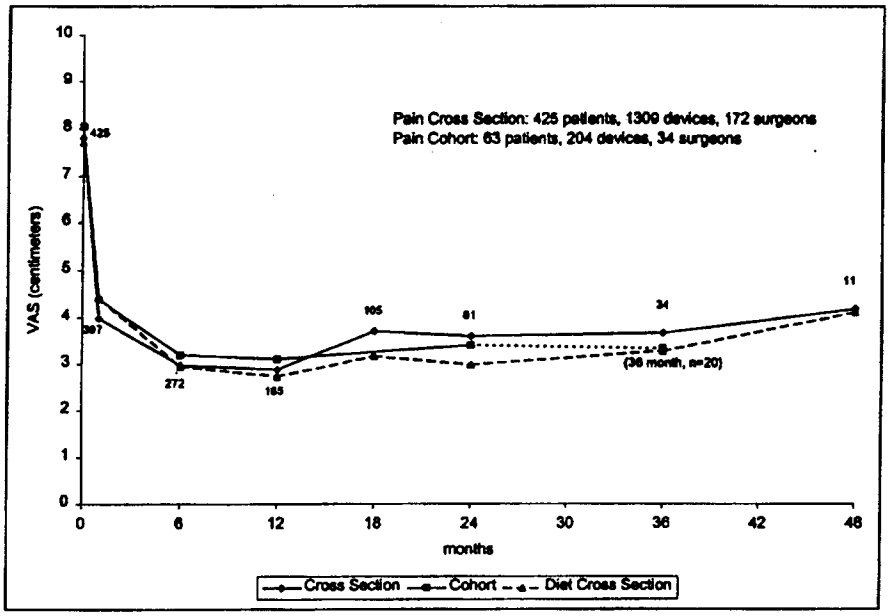


Table 1: Total Joint, Pain and Diet Cross Section Data

	Pain							
Months	0	1	6	12	18	24	36	48
Mean	7.8	3.9	3.0	2.9	3.7	3.6	3.7	4.2
n	425	397	272	185	105	81	34	11
	Diet							
Months	0	1	6	12	18	24	36	48
Mean	7.7	4.4	2.9	2.7	3.2	3	3.3	4.1
n	386	363	258	180	105	78	34	11

Table 2: Total Joint, Pain Cohort Data

Pain					
0	1	6	12	24	36
8.0	4.4	3.2	3.1	3.4	3.3
63	63	63	63	63	20

Improvement in Interincisal Opening: Total Joint Reconstruction

From the Cross-section data set, there is a marked improvement in the interincisal opening at 6 months after surgery, as demonstrated by Figure 2. Patients appear to reach their greatest improvement at 6 months after surgery and maintain that level of improvement through 4 years implant duration. Due to the small sample size at 4 years, the slight decrease at this time period is thought not to be significant. A similar trend of improvement in opening is demonstrated with a cohort of 57 patients with complete data through 2 years implant duration, Table 4. Approximately one-third of the cohort has

complete data at 3 years. By applying a Test of Contrasts to the 2-year cohort, a significant improvement in opening is demonstrated at every time period when compared to the pre-op value, $p<0.0001$. Additionally, an ANOVA F-Test was applied to the cohort. The overall test is significant at $p<0.0001$.

Figure 2: Total Joint, Improvement in Opening

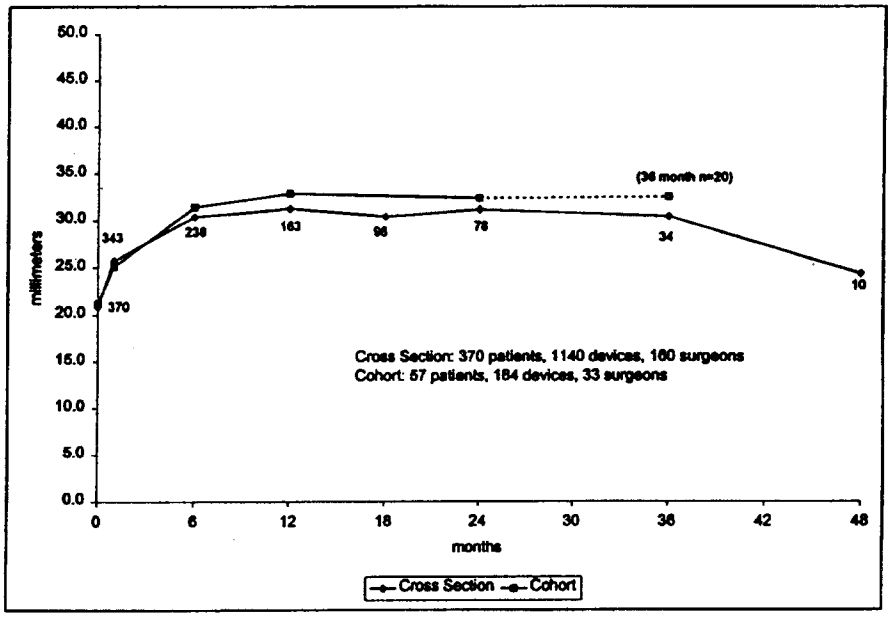


Table 3: Total Joint, Opening Cross-Section Data

Opening								
Months	0	1	6	12	18	24	36	48
Mean	20.9	25.8	30.4	31.2	30.4	31.1	30.4	24.3
n	370	343	238	163	98	78	34	10

Table 4: Total Joint, Opening Cohort Data

Opening					
0	1	6	12	24	36
21.2	25.1	31.4	32.8	32.4	32.5
57	57	57	57	57	20

Prospective Study

Demographic data is available from 43 subjects receiving a metal-on-metal total joint replacement. The mean age of this population is 44 ±13 years with a range of 24 to 74 years. The majority, 40 (93%), are female and caucasian, 37 (86%). There are two (2) African-Americans and two (2) Hispanics, and one (1) Native-American. The most frequently reported indications for total joint replacement are previously failed implant surgery, 31%; recurrent fibrous or bony ankylosis, 29%; degenerative joint disease, 13%; and trauma, 9%. The remaining 18% included resorptive joint pathology, inflammatory arthritis, internal derangement, and unreported.

Reduction in Pain and Diet Restriction: Total Joint Reconstruction

On average, for patients with total joint replacements, there has been a 64% reduction in pain and diet restriction by the 6-month post-op visit, Figure 3. Between 12 and 18 months, however, the mean pain and diet scores appear to increase generally above 3cm and then return to near the 6-month level by 24 months. A comparison of the historical data from patients with pain scores >3.0cm at 12 months and those with pain scores of ≤3.0cm at 12 months indicates that all 10 patients presenting with pain scores >3.0cm at

12 months are all multiply operated patients and 7 of the 9 patients presenting with pain scores ≤3.0cm at 12 months are multiply operated. However, of the former group (>3cm), besides being multiply operated, 6 of the 10 also had previously failed implant surgery, whereas of the latter group (≤3.0cm), only 1 of the 7 patients that are multiply operated had experienced failed implant surgery. All other confounding variables associated with the patients histories such as trauma, degenerative disease, ankylosis, osteochondritis dessicans or avascular necrosis, are of similar frequency among both groups. Therefore, it appears that those patients who have experienced previously failed implant surgery have a less stable post-op course than those patients who did not. A similar anomaly in the data at 18 months is also seen with the registry data for total joint replacement, but not as marked, Figure 4. The results reported to date suggest that multiply operated patients may not experience as great a reduction in pain. The results are interim results and final conclusions cannot be drawn until all patients have completed at least 3 years and the data are collected and analyzed.

Figure 3: Reduction in Pain, Total Joint Replacement

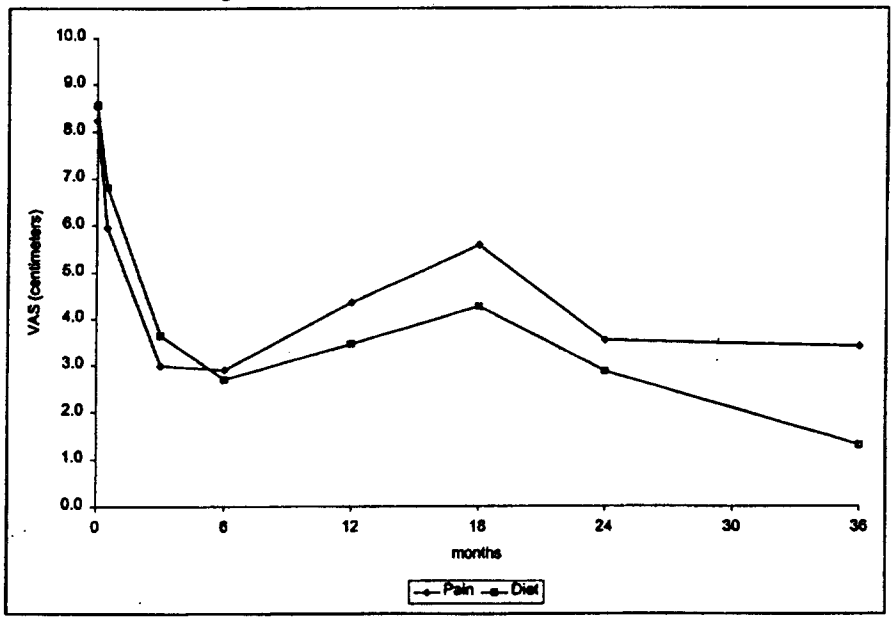


Table 5: Mean values, Reduction in Pain, Total Joint

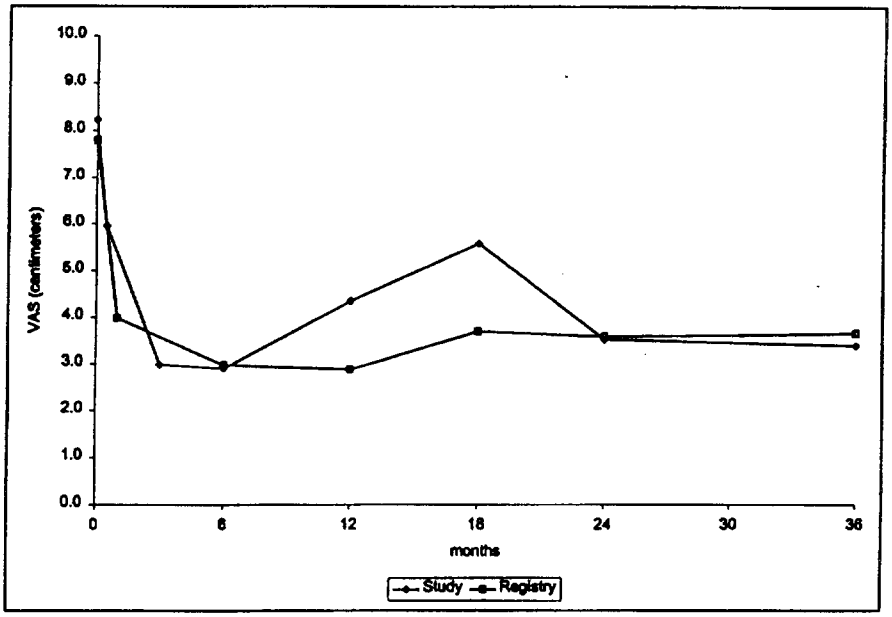
Pain								
Months	0	0.5	3	6	12	18	24	36
Mean	8.2	6.0	3.0	2.9	4.3	5.6	3.5	3.4
N	42	39	29	22	19	8	10	2

Table 6: Mean values, Reduction in Diet, Total Joint

Diet							
0	0.5	3	6	12	18	24	36
8.6	6.8	3.6	2.7	3.4	4.3	2.9	1
42	39	29	22	19	8	10	2

Note: There were only 42 pre-op pain and opening measurements from 43 patients. One patient failed to record a pre-op pain or opening measure; however, pain and opening were subsequently reported post-op through 18 months follow up for this patient.

Figure 4: Pain Reduction, Total Joint, Clinical Study and Registry Data



Improvement in Interincisal Opening: Total Joint Reconstruction

A patient's interincisal opening is measured in millimeters using either a Therabite scale or E-Z flex system. Measurements are taken at the pre-op visit, within 10 days post-op, then at 3, 6, 12 18, 24, and 36 months after implant. On average, by the 3-month post-op visit there is a significant improvement in opening, Figure 5. These trends are similar to the results presented with the TMJ Registry data, from those patients implanted with a total joint prosthesis, Figure 6. This trend of improvement continues through 36 months post-implant, Table 7.

Figure 5: Improvement in Opening, Total Joint replacement

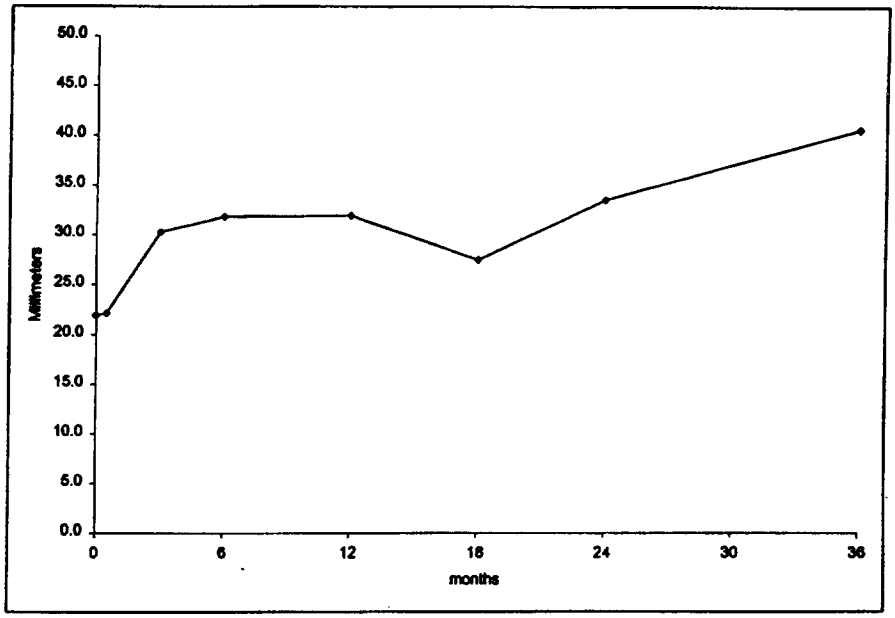
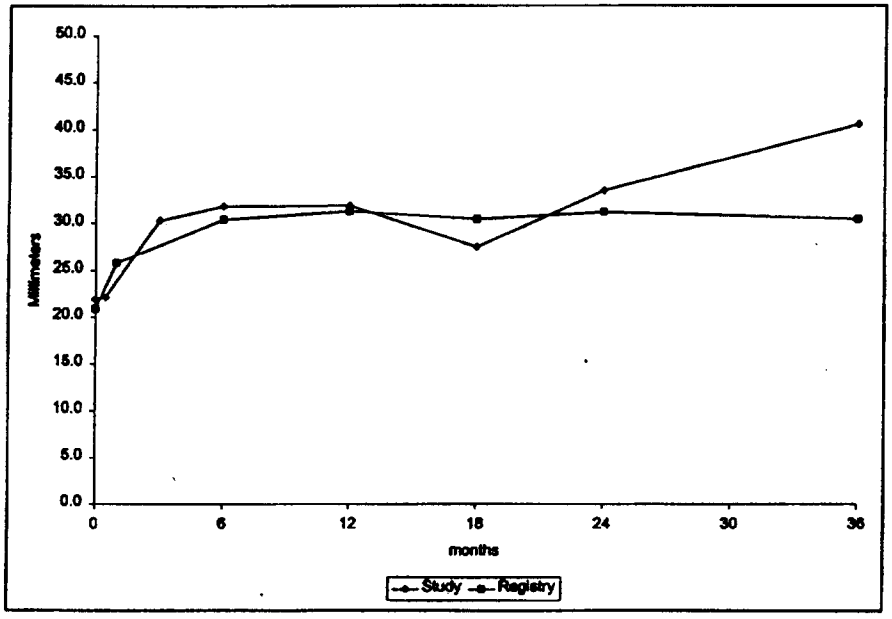


Table 7: Opening Mean values, Total Joint replacement

Opening								
Months	0	0.5	3	6	12	18	24	36
Mean	21.9	22.1	30.3	31.8	31.8	27.4	33.4	40.5
N	37	40	30	22	19	9	12	2

Figure 6: Improvement in Opening, Total Joint, Clinical Study and Registry Data



8. INFORMATION FOR USE

The TMJ Metal-on-Metal Total Joint Replacement System is Comprised of the TMJ Fossa-Eminence Prosthesis ™ and the TMJ Condylar Prosthesis™.

This Instructions for Use is intended to give you some answers for the use of TMJ Implants, Inc.'s TMJ Metal-on-Metal Total Joint Replacement System. However, this is not intended to be an exhaustive, or comprehensive treatise on this subject of alloplastic joint reconstruction.

Prior to Surgery

Warning

Patients with suspected sensitivity to metals, such as Nickel, should undergo appropriate testing for sensitivity to Co-Cr-Mo alloy. Upon request, TMJ Implants, Inc. will supply a sample of this alloy and/or the chemical composition for pre-operative allergy testing. The device should not be used in patients who test positive for Co-Cr-Mo alloy sensitivity.

There are instances where this technique is not recommended due to prior surgical procedures and the need to place prostheses in less than optimal angles and positions, or in cases where systemic medical disease would contraindicate this implant procedure in the view of the operating surgeon. The operating surgeon must make this evaluation. It is the surgeon's responsibility to determine the need for patient specific implants given anatomical considerations or unusual masticatory forces in a given patient.

Patients undergoing local or general anesthesia, prolonged dental therapy, extraction of teeth, or those patients using mechanical devices which create abnormal forces within the joint need to be alerted to possible injury to the joint or prosthesis due to those unusual forces.

The TMJ Metal-on-Metal Total Joint Replacement System is intended for total joint replacement. The TMJ Condylar Prosthesis must be implanted in conjunction with a TMJ Fossa-Eminence Prosthesis manufactured by TMJ Implants, Inc.

All TMJ Metal-on-Metal Total Joint Replacement Prostheses, screws, drills, and the Condyle sizers are provided sterile.

Prior to use, the Fossa sizer, and the screwdrivers and holders for both prostheses must be sterilized in their respective containers in accordance with hospital standards for steam sterilization. Steam sterilization should be accomplished at 121° C for 30 minutes.

Caution - The surface of the device must remain clean and free of debris prior to implantation.

Caution - The implant must be handled only with talc-free gloves to avoid introduction of talc into the implantation site.

Caution - The prostheses must be protected from scratching or bending prior to and during surgical implantation, as such damage in certain circumstances may cause weakening or fatigue of the metal or fracture of the part.

During Surgery

The location of each component included in the TMJ Metal-on-Metal Total Joint Replacement Prosthesis System is shown on a diagram on the inside lid of the respective package.

The TMJ Fossa-Eminence Prosthesis used in conjunction with the TMJ Condylar Prosthesis should be placed and secured first.

PLACING THE TMJ FOSSA-EMINENCE PROSTHESIS COMPONENT OF THE TMJ METAL-ON-METAL TOTAL JOINT REPLACEMENT SYSTEM

A detailed Patient-Specific Manual is available which provides instructions for CT scanning patients, and describes how to prepare the Anatomical Bone Model prior to implant design.

It is the responsibility of the surgeon to become familiar with the surgical techniques for implantation of these devices through attendance at surgical demonstration courses, use of instructional video, consultation with experienced associates and manipulation of replica models.

The normal preauricular or endaural incision and approach to the joint is accomplished. Exposure of the entire zygomatic process of temporal bone lateral to the joint is necessary to facilitate placement of the TMJ Fossa-Eminence Prosthesis.

When the joint is fully exposed try the sizer for fit. Take your time at this point. Find the sizer that fits the bone most accurately with at least 3-point contact and allows the condyle to function smoothly, without dislocation of the joint and provides suitable stability. At this stage check the occlusion very carefully. Ensure the occlusion remains as seen pre-operatively or as desired post-operatively. If not, determine why.

After selecting the proper sizer, check the laser-etched number on the sizer and have the nurse or anesthesiologist record it for future reference.

Noting the etched number from the correct-fitting sizer, select the same numbered TMJ Fossa-Eminence Prosthesis, which has been packaged sterile. Try it for accuracy of fit, proper occlusion, and mobility of the condyle.

It is strongly recommended that at least four (4) Fossa-Eminence screws be used where practical to achieve firm fixation of the TMJ Fossa-Eminence Prosthesis. Be sure to use the screws provided to insure compatibility of the metals. Caution should be used so as not to force the screw in place with too much pressure as the screw head could fracture. Always drill the hole slightly deeper than the length of the screw. When the implant has been secured in place, check again for proper jaw function and proper occlusion. Be sure to use the drill bits provided for preparing the screw holes. Be diligent in this surgery to avoid injury to important adjacent structures i.e. middle cranial fossa, ear structures, facial nerve, and middle meningeal artery.

The TMJ Fossa-Eminence Prosthesis must be secured only through the use of the drills and screws supplied by TMJ Implants, Inc. The screws and drills used with the TMJ Fossa-Eminence Prosthesis have been specifically selected by size to ensure correct fixation of each prosthesis when used as directed. Any use of substitute drill bits or

screws not supplied by TMJ Implants, Inc. in the TMJ Fossa-Eminence Prosthesis System may result in less than optimal long-term results and may adversely affect the performance of the prosthetic device.

PLACING THE TMJ CONDYLAR PROSTHESIS COMPONENT OF THE TMJ METAL-ON-METAL TOTAL JOINT REPLACEMENT SYSTEM

A detailed Patient-Specific Manual is available which provides instructions for CT scanning patients, and describes how to prepare the Anatomical Bone Model prior to implant design.

It is the responsibility of the surgeon to become familiar with the surgical techniques for implantation of these devices through attendance at surgical demonstration courses, use of instructional video, consultation with experienced associates and manipulation of replica models.

Once the wound has been opened to expose the remaining natural condyle and the occlusion have been fixed, then remove enough condyle height to allow a condylar sizer with its 13mm head to be placed in position. The condylar sizer will allow you to determine which length of the TMJ Condylar Prosthesis will most accurately fit the patient's mandible.

When the correct condylar length has been determined by use of the condylar sizer, you are now ready to place the actual TMJ Condylar Prosthesis.

It is recommended that the head of the TMJ Condylar Prosthesis be placed into the prosthetic glenoid fossa portion of the TMJ Fossa-Eminence Prosthesis with all interposing soft tissue removed. The Condylar Prosthesis articulating surface should preferably be centered in the Fossa and should not contact the screws of the Fossa-Eminence Prosthesis.

The proper placement of the condylar head into the TMJ Fossa-Eminence Prosthesis, assures that the head does not contact any screw heads during function. It is important to fix the TMJ Condylar Prosthesis to the ramus of the mandible with as many screws as possible. It is strongly recommended that at least six (6) condylar screws for the Universal Condylar Prosthesis and nine (9) condylar screws with the Christensen-Chase Condylar Prosthesis be used, where practical, to achieve firm fixation of the TMJ Condylar Prosthesis. Care must be taken to secure at least 3 screws in the topmost holes, where practical.

The Christensen/Chase TMJ Condylar Prosthesis System Kit is available in either a left or right-sided set. The head of each of these prostheses is identical in size and shape. As with the Universal System, there are three lengths available: 45mm, 50mm, and 55mm. The Christensen/Chase prostheses differ from the Universal prostheses in that the Christensen/Chase devices have an angled extension on the distal portion of the flange, allowing the physician to more closely follow the patient's natural mandibular structure, and to provide anchoring options in the absence of bone.

The flange direction of the Condylar Prosthesis is generally ideal when it parallels the posterior margin of the mandibular ramus.

The TMJ Condylar Prosthesis must be secured only through the use of the drills and screws supplied by TMJ Implants, Inc. The screws and drills used with the TMJ Condylar Prosthesis have been specifically selected by size to ensure correct fixation of each prosthesis when used as directed. Any use of substitute drill bits or screws not supplied by TMJ Implants, Inc. in the TMJ Condylar Prosthesis System may result in less than optimal long-term results and may adversely affect the performance of the prosthetic device.

If both sides of the mandible area are to reconstructed, the contralateral side is operated in a similar fashion.

The mandible should now be mobilized and forced open, observing the maximum range of opening. Should mobility be limited, the surgeon should assess the possible need for coronoidectomies and/or relief of adhesions to the ramus. Observe the movement of the condylar head(s) to be sure that dislocation does not occur. The fixation appliances may now be removed.

Additional Considerations

The placement of a fat graft around the implants at surgery may reduce the occurrence of subsequent adhesion or even ankylosis. For those patients susceptible to heterotopic bone formation, appropriate fat grafts and radiation therapy should be considered.

Occasionally, longer screws will be necessary to engage bone. It is important that the surgeon exercise great care to prevent injury to deeper vital structures. Care must be exercised not to penetrate or impinge any auditory structure, middle cranial fossa, or any neuro/vascular structures.

When performing an excision of bone in the area of the normal glenoid fossa and condyle, especially in cases of bony ankylosis, the surgeon must exercise great care to avoid penetration into the middle cranial fossa, the auditory canal, or other vital structures.

Post Surgery

Accepted surgical practice should be followed in post-operative care.

After the total joint replacement is completed, all instruments must be thoroughly cleaned, decontaminated and sterilized in accordance with the following procedures outlined below.

9. CLEANING AND STERILIZATION

Contents must be stored between 10° and 32° C (50° - 90° F) and 20% to 80% relative humidity.

The TMJ Condylar Prostheses, condylar sizers, screws and drills and the Fossa Eminence Prostheses screws and drills are packaged sterile. Care must be taken to assure packaging remains undamaged to ensure sterility.

Cleaning Instructions for Reusable Instruments

For your safety, be familiar with the procedures for handling contaminated materials at your facility prior to utilizing these instructions.

Clean instruments in the provided autoclave trays as soon as possible after use. Avoid allowing soiled instruments to dry. Immerse into or use towels dampened with deionized or distilled water to keep soiled instruments moist prior to cleaning.

Manually wash the templates and instrumentation with mild detergent following the detergent manufacturer's instructions for use. pH neutral cleaners are recommended. Follow the detergent manufacturer's recommendations for use dilution. Enzyme cleaners (e.g. Enzol™) prepared as recommended by the manufacturer may be used to aid in cleaning. Avoid exposure to acidic or alkaline solutions and solutions containing chlorides, bromides, or iodine.

Allow the devices to soak for one minute. Use a soft bristle brush to manually clean the devices while immersed in the cleaning solution, paying particular attention to crevices and other hard-to-clean areas. Clean the devices until all adherent visible soil is removed.

After washing, thoroughly rinse instruments for one minute under lukewarm, clean, deionized or distilled water.

Sterilization Instructions for Reusable Instruments

Visually inspect for cleanliness, especially in recesses. Check instruments thoroughly for damage, (i.e. chips, cracks, corrosion, surface wear, etc.) especially instruments with moving parts or interfits such as a quick–connect mechanism. Do not use instruments that have been damaged. Damaged instruments should be replaced.

Dry completely with a clean, soft cloth before sterilization.

Reusable instruments, e.g., the Fossa sizer, and the screwdrivers and holders, for both prostheses must be sterilized in their respective containers.

The recommended prevacuum sterilization cycle parameters are wrapped at 132°C for 4 minutes with a 20 minute drying time. The recommended gravity flash sterilization parameters are unwrapped at 121°C for 10 minutes with no drying time.

It is recommended not to exceed 5 stacked trays per sterilization run.

Should you have any questions, please feel free to call us at
(303) 277-1338 or (800) 825-4865.

TMJ IMPLANTS, INC. ANATOMICAL MODEL CT SCANNING PROTOCOL

Please take the time to read this entire protocol. The quality of anatomical model we can generate depends on the quality of scan we receive. Please have the CT Technologist call one of our technicians toll-free at 1-800-825-4865 prior to using this protocol for the first time.

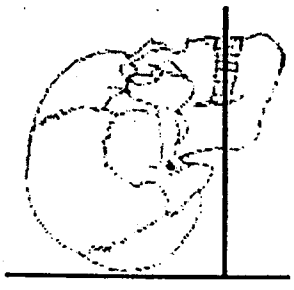
SCANNING GUIDELINES

1. If using this protocol for the first time, please archive the original data to your files until TMJ Implants confirms the transfer.
2. Patient must remain completely still through the entire scan. If patient motion occurs the scan must be restarted.
3. Please scan from bottom of mandible to 1.0 cm above joints (usually midorbit).
4. Please archive entire exam.
5. Please archive uncompressed image data (NOT raw data) onto appropriate media accepted for your scanner.
6. The magnetic tape or optical disk should be sent via express shipment to TMJ Implants.

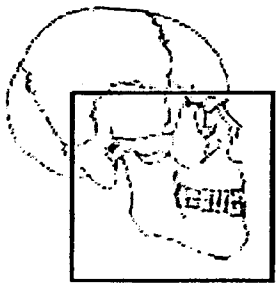
SCANNING PARAMETERS (Axial or Helical)

FOV:	25 cm
Gantry Tilt:	0
Scan Spacing:	1 mm
Slice Thickness:	1 mm
Algorithm:	Standard (Not Bone or Detail)
MA/KVP:	120-150 MA / 120 KVP
Pitch:	1:1

PATIENT POSITIONING



AREA OF INTEREST



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SUPPORTED SCANNERS

Models	Media Type(s)
GENERAL ELECTRIC	
Lightspeed	2
CT/i	1,2
Hispeed Advantage	1,3
Hilight Advantage	1,3
Prospeed	1,3
SIEMENS	
Volume Zoom*	2
Somatom Plus 4*	1
Somatom HiQ*	1
Somatom DRH*	1
Somatom AR*	1
*uncompressed data only!	
PICKER	
MX 8000 (Marconi)	2*
PQ 6000	4
PQ 5000	4
PQ 2000	4
*Archive through Omni Pro workstation only! Call for archiving instructions.	
ELSCINT	
Excel / Elect*	2,5
Elite*	2,5
*Archive through Omni Pro workstation only! Call for archiving instructions.	
PHILIPS	
Tomoscan TX, CX, LX, SR	1
TOSHIBA	
Xpress SX / Aspire*	2
*TSG-C format only	

MEDIA TYPES

1 - 5.25" Optical Disk (Pioneer, etc.)
2 - 5.25" Optical Disk (Maxoptix, etc.)
3 - 4mm DAT Tape
4 - 8mm DAT Tape
5 - 3.5" Floppy Disks

Please call regarding other scanners not listed. Internet transfer may be possible, please call for more information.